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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/424,840	12/03/1999	PETER BERCHTOLD	P564-9049	8688

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EXAMINER
HELMS, LARRY RONALD

ART UNIT	PAPER NUMBER
1642	22

DATE MAILED: 07/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/424,840	BERCHTOLD ET AL.	
	Examiner	Art Unit	
	Larry R. Helms	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 May 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12,17,18,20-25 and 28-36* is/are pending in the application.

4a) Of the above claim(s) *1-12,17,18,20-25,28 and 29* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *30-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. Claims 13-16, 19, 26-27 have been canceled.

Claims 30-36 have been added.

2. Claims 1-12, 17-18, 20-25, 28-29 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions. Election was made **without** traverse in Paper No. 14.

3. The text of those sections of Title 35 U.S.C. code not included in this office action can be found in a prior Office Action.

4. The following Office Action contains some NEW GROUNDS of rejection.

Rejections Withdrawn

5. The rejection of claims 13-15, 26 under 35 U.S.C. § 101 because the claimed invention is directed to non-statutory subject matter is withdrawn in view of the amendments to the claims.

6. The rejection of claims 26-27 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is withdrawn in view of the amendments to the claims.

7. The rejection of claims 13-16, 19, 26-27 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject

matter which applicant regards as the invention is withdrawn in view of the amendments to the claims.

Response to Arguments

8. The rejection of newly added claims 30-36 under 35 U.S.C. 112, first paragraph, is maintained and made again.

The response filed 5/9/03 has been carefully considured but is deemed not to be persuasive. The response states that CDR3 is the only region critical for bonding to an antigen and specific variations in the amino acid sequence of a CDR3 region have been found to be tolerable (see page 5 of response). In response to this argument, the specification does not teach that CDR3 of the heavy chain binds antigen by itself. In addition, the specification does not teach any alterations in CDR3 that result in antigen binding. The only two sequences are SEQ ID NO:31 and 32 and no alterations are taught or where in the sequence an alteration would be tolerated. The response also does not address the unpredictability in the art as evidenced by Rudikoff and Amit.

The response further states that the antibodies have been shown to retain the desired binding and one could use the composition for in vivo use (see page 5 of response). In response to this argument, while the entire antibodies may bind antigen, the claims encompass only a CDR3 region and these fragments are not enabled. In addition, the response did not address the concern that the entire antibody is needed to elicit anti-ids as evidenced by Chatterjee et al.

Therefore, in view of the lack of predictability in the art as evidenced by Rudikoff et al, Amit et al, and Chatterjee et al and the lack of guidance in the specification one of skill in the art would be required to perform undue experimentation in order to practice the claimed invention.

9. The rejection of newly submitted claims 30-36 under 35 U.S.C. 102(b) as being anticipated by Berchtold (Blood 74:2414-2417, 1989) is maintained.

The response filed 5/9/03 has been carefully considured but is deemed not to be persuasive. The response states Berchtold discloses polyclonal antiserum and does not disclose or suggest monoclonal antibodies or the sequence of the claimed antibodies and the human antibodies of the present invention were obtained from healthy human donors while Berchtold were from diseased patients (see page 5-6 of response). In response to this argument, it is immaterial if the antibodies are polyclonal or monoclonal because the claims are directed to an antibody. In addition it is immaterial that the antibodies were from a diseased patient because the antibodies of the instant application and those of Berchtold are directed to the same antigen. In the rejection the burden was properly shifted to applicant to show a distinction between the antibody in the prior art and the claimed antibody. Such a distinction is not made and as such the rejection is maintained.

10. The rejection of claims newly added claims 30-36 under 35 U.S.C. 102(b) as being anticipated by Nugent et al (Blood 70:16-22, 1987) is maintained.

The response filed 5/9/03 has been carefully considured but is deemed not to be persuasive. The response states it is extremely unlikely that the 5E5 disclosed by Nugent would have the same CDR3 sequence as the antibody of the present invention and the human antibodies of the present invention were obtained from healthy human donors while Nugent were from diseased patients (see page 6 of response). In response to this argument, it is immaterial that the antibodies were from a diseased patient because the antibodies of the instant application and those of Nugent are directed to the same antigen. In the rejection the burden was properly shifted to applicant to show a distinction between the antibody in the prior art and the claimed antibody. Such a distinction is not made and as such the rejection is maintained.

The following is a NEW GROUND of rejection

11. Claims 30-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claims 30-36 are indefinite for reciting "able to bind to GPIIb/IIIa of a human antibody or a fragment thereof" in claims 30 and 35 because the exact meaning of the phrase is not clear. Does the antibody bind human GPIIb/IIIa or an antibody to human GPIIb/IIIa or is the antibody a human antibody that binds GPIIb/IIIa or some other meaning?

b. Claims 30 and 36 are indefinite for reciting "wherein the antibody or antibody fragment is encoded by a nucleic acid which encodes a heavy chain" in claim 30 or "further comprising a second antibody or antibody fragment subunit encoded by a nucleic acid which encodes a light chain" in claim 35 because the exact meaning of the phrases are not clear. It is unclear how an antibody can be encoded by a nucleic acid that encodes a heavy chain or a light chain. Antibodies comprise heavy and light chains not just light or heavy chains. In addition it is not clear if claim 35 needs a second antibody molecule or if the claim is for a light chain that is to pair with the heavy chain in claim 30. If another antibody is needed than what does it bind to?

c. Claim 31 is indefinite for reciting "further comprising the variable domain of the H chain" because claim 30 recites the heavy chain comprising a CDR3 and as such the claim has the variable region of the H chain already and the antibody (presumably) is human and as such would have CDR3 and the rest of the variable domain unless claim 30 is only claiming a fragment which is CDR3 only.

Conclusion

12. No claim is allowed.

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Larry R. Helms, Ph.D, whose telephone number is (703) 306-5879. The examiner can normally be reached on Monday through Friday from 7:00 am to 4:30 pm, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

15. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the

Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 308-4242.

Respectfully,

Larry R. Helms Ph.D.

703-306-5879